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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/756,793	01/13/2004	John W. Babich	346715-0539	1512

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/756,793

Applicant(s)

BABICH ET AL.

Examiner

Celia Chang

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 September 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 159-164 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 159-164 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Applicant's election without traverse of Group I, claims 159-164 in the reply filed on Sept. 6, 2006 is acknowledged.

Claims 1-158 have been canceled. Claim 159 as currently amended and claims 160-164 are pending.

2. Claims 159-164 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

There is insufficient description for the scope as now amended. Please note that on pages 9-16 of the specification wherein the compounds of formula A and analogous structural compounds were describe, the preferred embodiment are limited to X is O compounds and no specific subgeneric scope for the instantly amended X are exclusively H₂ were found. The only antecedent basis for X are H₂ compound is found on page 7, compound 9. No subgeneric description founds antecedent basis in the specification, thus, are considered new matter. As set forth by In re Smith 173 USPQ 679, the guideline is that a genus may not support a subgenus even though there is a disclosed species within the subgenus. A careful survey of the specification founds description in formula A and analogous compounds, no description of the instant subgenus can be found.

Further, there is no definition for the term radionuclide in terms of elements, size, ionic or chemical nature of this Markush element. The elements find antecedent basis to this term are limited to Rhenium and Technetium and only Rhenium has been exemplified with the instant formula A or compound 9.

Therefore, to the extend that claims 159-164 wherein the formula A is other than compound 9, and to the extend the radionuclide is other than Re or Tc, the claims contain new matter. Removal of new matter is required. In re Russmussen 210 USPQ 325.

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3. Claim 161 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term “imaging brain tissue” is confusing. A method claim must include the steps of how such process is being carried out. The term imaging does not offer any steps or effects of such steps, dosage or site of administration. Besides, if the compounds are dopamine transporter ligands, how does such binding provide imaging of the whole brain? The scope of the claim is indefinite.

4. Claims 159-164 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The standard for determining whether the specification meets the enablement requirement was cast in the Supreme Court decision of *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916), where the Supreme Court looked to whether the experimentation needed to practice an invention was undue or unreasonable. *Id.* An invention must be described so that any person skilled in the art can make and use the invention without undue experimentation. *In re Wands*, 858 F.2d at 737, 8 USPQ2d at 1404 (Fed. Cir. 1988). As stated in the MPEP 2164.01(a) “There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. The analysis must consider all the evidence related to each of these factors, and any conclusion of nonenablement must be based on the evidence as a whole. *Id.* at 740, *Id.* at 1407. The factors to be considered herein are those set forth as the *In re Wands*, 8 USPQ 2nd 1400 (1988) decision.

The analysis is applied to the instant case.

Nature of invention

The claims are drawn to a radionuclide complex of a compound represented by formula A and method of using such a complex for brain imaging.

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The state of the art and predictability

The state of the art in biological imaging material indicated that the particularity of the compound i.e. its chelating nature and the specific elements carrying radioactivity must form with such particularity in size, charge and stability as to be operable in carrying the emitting material to the site for photon emission tomography. There is no evidence in the field that compounds with diverse structure or radioelement with diverse size can predict such photon emission tomography requirement. See Kung et al., Cutler et al. or Sohn attached.

The amount of guidance and working examples

In the specification, no definition was given to the size, charge or stability required by the term "radionuclide" with only two elements being exemplified, Re and Tc. The only compound for X is H₂ is compound 9, disclosed on p.7. In addition, compound 9 is a dopamine transporter ligand for which the binding to other anatomical structure of the brain has not been described or supported by documents of record. The particularity in radiolabeling of the dopamine transporter system finds little generalization that structural diverse compounds or diverse radioactive elements can be operable for such process. Further, while binding of dopamine transporter system can provide visual evaluation in diagnosis and monitoring of disease such as Parkinson's disease, has not been widely accepted to provide visual evaluation for all possible brain tissue deviation.

Therefore, for the scope of the claims beyond compound 9 with radionuclide Re, and the photon emission tomography of the dopamine transporter system, the specification provided no enabling support.

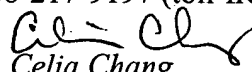
5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas McKenzie, Ph. D., can be reached on 571-272-0670. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang


Celia Chang
Primary Examiner
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